

**FISCAL NOTE
PRIVATE COST**

- I. Department Title: 19 – Department of Health and Senior Services**
Division Title: 25 – State Public Health Laboratory
Chapter Title: 36 – Testing for Metabolic Diseases

Rule Number and Title:	19 CSR 25-36-010 Testing for Metabolic and Genetic Disorders
Type of Rulemaking:	Proposed Amendment

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the rule by the affected entities:
108 78 46 1,470	Hospitals Clinics Midwives Physicians	\$1,330,560 annually with projected first year fee increase; \$383,040 additional annually with projected second year fee increase; up to \$2,419,200 annually in the aggregate with implementation of additional fee increases up to the established fee cap

III. WORKSHEET

Projected first year increase: 80,640 specimen collection forms annually x \$16.50 fee increase = \$1,330,560 annually

Projected second year increase: 80,640 specimen collection forms annually x \$4.75 fee increase = \$383,040 additional annually

Maximum increase: 80,640 specimen collection forms annually x \$30 fee increase = \$2,419,200 annually in the aggregate

IV. ASSUMPTIONS

- Estimated 80,640 specimen collection forms each year based on previous years.
- Number of entities affected estimated by number of previous submitters.
- The cost (established fee) of newborn screening will most likely be passed on to health insurance companies by the entities listed above.
- The newborn screening fee provides the funds necessary for the Department of Health and Senior Services to perform the established laboratory screening tests and associated follow-up services for a positive test result.

- The rule changes the fee cap ceiling from \$65 per specimen collection form to a cap of \$95 per specimen collection form (possible total fee increase of \$30 per collection form).
- The increases anticipated in the first two years (\$16.50 year 1; \$4.75 year 2) are needed to support the costs of testing and follow-up services performed for Lysosomal Storage Disorders (LSD). LSD screening is being implemented as required by HB 716 passed in 2009.
- Additional fee increases will be implemented by DHSS as necessary to financially support inflationary costs and additional testing that may be added to the newborn screening panel in the future. Additional tests would only be implemented after review and approval by the DHSS Genetics Advisory Committee in order to remain in compliance with such recommendations as the Recommended Uniform Screening Panel (RUSP) of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children or as required by legislation passed by the Missouri General Assembly.